Test Name	Test Code	Effective Date
Hepatitis C Viral RNA, Genotype, LiPA	**TH41-7**	**Immediately**

Test code, TH41-7 Hepatitis C Viral RNA, Genotype, LiPA will be retired. The suggested alternate is in house test code, 2161-8 Hepatitis C Genotype.

	Previous Test Information	New Test Information
Primary Container	PPT - White Top (PPT)	ALQE - Aliquot Plasma-EDTA-Lavender Top
Alternate Container	ALQE - Aliquot Plasma-EDTA-Lavender Top , ALQS - Aliquot Tube-Serum	ALQS - Aliquot Tube Serum, PEDS - Microtainer - Pediatric SST, PPT - White Top (PPT), SST - SST Tube
Minimum Volume	0.6mL	2mL
Turn Around Time*	9 days	5-7 days
Transportation Temp	Refrigerate	Refrigerate
Stability	14 days refrigerate, 42 days frozen	7 days refrigerate, 14 days frozen
Methodology	Reverse transcription polymerase chain reaction	Line Probe Assay utilizing reverse-hybridization
Reference Range	Not Detected	Not Detected
Collection Instructions	PPT: After collection centrifuge at high speed for 8-10 min. Remove plasma and submit in aliquot tube. Label it plasma.	ALQE: Centrifuge lavender-top at high speed for 15 minutes. Transfer plasma into plastic transfer tube. Label with date/time collected, EDTA PLASMA and patient's name.
Profile Components	N/A	N/A
CPT Code(s)**	87902	87902
Clinical Utility (If applicable)	Hepatitis C Viral RNA, Genotype, LiPA® - Determination of hepatitis C genotype is often required to select the most appropriate direct acting agent(s) (DAA) for the treatment of hepatitis C. Some DAA's are only effective for the treatment of hepatitis C genotype 1, whereas others may be used for additional genotypes. Refer to the package inserts of the relevant DAA's for guidance.	N/A

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Test Name	Test Code	Effective Date
Sequential Screen Part 1 **Combined First Plus** **Combined First** **Integrated Part 1**	**8602-5** **8622-3** **6246-3** **6375-0**	**1/1/2025**

To all sonographers who submit nuchal translucency measurements:

In April 2023, we sent an announcement to all clients, explaining that in December 2023, the Perinatal Quality Foundation and the NTQR program would cease to exist. We noted that: "Sonographers who have heretofore been credentialed through NTQR, no longer will have a quality maintenance program, unless they register with the FMF program." In the announcement, we stated that we would continue to report risk results for NTQR certified sonographers for a calendar year after the closure of NTQR.

As of January 1st, 2025, we will no longer be able to use NT data from sonographers who have not been certified through the FMF program. Therefore, we urge all uncertified sonographers to obtain their FMF certification ASAP. You can begin the process using the link below:

https://fetalmedicine.org/nuchal-translucency-scan

	New Test Information
Primary Container	SST
Minimum Volume	2.0mL
Turn Around Time*	4 days
Transportation Temp	Refrigerate
Stability	7 days
Methodology	Chemiluminescence
Collection Instructions	SST: Fill tube, invert gently 5 times, label with patient name, let stand for minimum of 30 minutes, maximum of 1 hr, spin for 10-15 minutes
CPT Code(s)**	**82105x1**

Test Name	Test Code	Effective Date
Epstein-Barr Virus Viral Capsid Antigen (VCA) Antibody (IgM)	**1678-2**	**Immediately**

Test code 1678-2 Epstein-Barr Virus Viral Capsid Antigen (VCA) Antibody (IgM) will be retired and the alternate suggested test code is in house test 0580-1 EBV Capsid Ab, IgM.

	Previous Test Information	New Test Information
Primary Container	SST - SST Tube	SST - SST Tube
Minimum Volume	0.5mL	1mL
Turn Around Time*	8 days	1 day
Transportation Temp	Refrigerate	Refrigerate
Stability	4 days Room temp, 7 days refrigerate, 30 days frozen	7 days refrigerate
Methodology	Immunoassay	Chemiluminescence

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Reference Range	<36.00 U/mL=Negative, 36.00-13.99=Equivocal, >43.99=Positive	<36.00 U/mL=Negative, 36.00-13.99=Equivocal, >43.99=Positive
Collection Instructions	SST: Fill tube, invert gently 5 times, label with patient name, let stand for minimum of 30 minutes, maximum of 1 hr, spin for 10-15 minutes.	SST: Fill tube, invert gently 5 times, label with patient name, let stand for minimum of 30 minutes, maximum of 1 hr, spin for 10-15 minutes.
CPT Code(s)**	86665	86665
Clinical Utility (If applicable)	Detection of primary infection with EBV	Detection of primary infection with EBV

Test Name	Test Code	Effective Date
HIV-1 genotyping assay and Profile Addition	**M396-0**	**Immediately**

We are pleased to launch M396-0, a new FDA-approved HIV-1 genotyping assay. This will now be replacing profile M392-9. The testing algorithm will be based on the results of the viral load run at BioReference. This new panel will eliminate the reflexing to the Archive assay (<500 copies/mL).

This assay is a next generation sequencing (NGS)-based test intended for use in detecting HIV-1 genomic mutations in the protease (PI), reverse transcriptase (NRTI and NNRTI) and integrase regions of the pol gene as an aid in monitoring and treating HIV-1 infection. This test is used in adjunct to the therapeutic management of patients diagnosed with HIV-1 Group M subtypes A-K infection, with various viral loads, in EDTA plasma specimens.

Profile code M396 HIV-1, RNA, Ultra Quant PCR Reflex To Genotype

- When viral load for HIV-1 RNA Ultra Quant PCR is >/= 1000 copies /mL test code TN88 HIV-1 Genotype (NRTI, NNRTI, PI, Integrase Inhibitors) will be added.
- When viral load for HIV-1, RNA, Ultra Quant PCR is >500 but <1000 copies/mL test code TQ70 will be added HIV-1 Genotype (NRTI, NNRTI, PI, Integrase Inhibitors)

Results should be used in conjunction with other available laboratory and clinical information and are not intended for use as an aid in the diagnosis of infection with HIV, to confirm the presence of HIV infection, or for screening donors of blood, plasma or human cells, tissues and cellular and tissue-based products.

	Previous Test Information	New Test Information
Primary Container	EDTA lavender top	EDTA lavender top
Minimum Volume	0.6 ml	0.8 ml
Turn Around Time*	13 days	12 days
Transportation Temp	2-8 degrees C	2-8 degrees C
Stability	Ambient 6 hours, after separation from cells ambient 24 hours, 2-8 degrees C for 5 days, frozen 4 months	Ambient 2 hours, after separation from cells 2-8 degrees C for 7 days, frozen for 1 month, avoid freeze thaw cycles
Methodology	Real-time PCR	Next generation sequencing (NGS)
Reference Range	Not Detected	Susceptible
Collection Instructions	Centrifuge lavender top at high speed for 15 minutes. Transfer plasma to plastic transfer tube. Label with date/time collected, EDTA PLASMA and patient's name.	Gently invert lavender top 8-10 times. Store tubes in upright position for up to 2 hours prior to centrifugation. Centrifuge at 1900 x g for 10 minutes at 2-8 degrees C. Transfer to plastic transfer tube and label with date/time collected, EDTA PLASMA and patient's name.
Profile Components	Protease, reverse transcriptase (NRTI and NNRTI), and integrase regions	Protease, reverse transcriptase (NRTI and NNRTI), and integrase regions
CPT Code(s)**	87900, 87901	0219U

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Clinical Utility (If applicable)	Management of HIV-1 infection. Identifies drug resistance to HIV-1 protease, reverse transcriptase, and Integrase genes.	Management of HIV-1 infection. Identifies drug resistance to HIV-1 protease, reverse transcriptase and integrase regions of POL gene.

Test Name	Test Code	Effective Date
TROPHERYMA WHIPPELII DNA, QUANT. PCR	**3487-6**	**Immediately**

Please note, test code 3487 will be retired with no recommended alternative.

Test Name	Test Code	Effective Date
HIV AG/AB 4th Generation	**B688-3**	**Immediately**

As a reminder, please draw a separate SST when ordering B688-3 to ensure timely completion of all testing requested.

	Previous Test Information
Primary Container	SST
Minimum Volume	1mL
Turn Around Time*	1 day
Transportation Temp	Refrigerate
Stability	7 days
Methodology	Electrochemiluminescence Immunoassay
Reference Range	Non-reactive
Collection Instructions	SST: Fill tube, invert gently 5 times, label with patient name, let stand for minimum of 30 minutes, maximum of 1 hr, spin for 10-15 minutes
CPT Code(s)**	**87389x1**
Clinical Utility (If applicable)	Used for simultaneous detection of HIV-1 p24 antigen, HIV Type 1 and HIV Type 2 antibodies

Test Name	Test Code	Effective Date
HCV Genotype	**Various**	**Immediately**

What is the testing algorithm for hepatitis C?

B125-6: Current NYSDOH and CDC guidance recommends a two-step testing sequence for diagnosis of hepatitis C infection. Testing is initiated with a hepatitis C antibody test. When this test is reactive, a hepatitis C RNA test is performed to confirm the diagnosis of current infection and determination of the Hepatitis C viral load.

For clinical follow-up, the Profile M432-3 can be ordered which will first run a viral load and if >500 IU/mL, will reflex to HCV Genotype.

HCV NS3 Drug Resistance for Genotype assays (i.e. J996-0, B610-7, J242-9, and K943-1) will now first require an HCV Viral load (3376-1) and HCV Genotype (2161-8) to be performed.

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Test Name	Test Code	Effective Date
Troponin-T	**2578-3**	**Immediately**

Test Code 2578-3 Troponin-T will be retired. The suggested alternate test code is TR21-8 Troponin T, High Sensitivity.

	Previous Test Information	New Test Information
Primary Container	ALQS - Aliquot Tube-Serum	GRLA - Lithium Heparin Plasma(Green top tube)
Minimum Volume	0.5 ml	1mL
Turn Around Time*	8 days	7 days
Transportation Temp	Refrigerate	Refrigerate
Stability	365 days Frozen	7 days Refrigerate, 365 days Frozen
Methodology	Immunoassay	Electrochemuluminescence Immunoassay
Reference Range	<0.01 ng/mL	Male <23 ng/L, Female <15 ng/L
Collection Instructions	Place 1-3 mL of serum in transport tube. Label as serum; refrigerate or freeze as required.	Collect using standard venipuncture techniques in lithium heparin tube only
Profile Components	N/A	N/A
CPT Code(s)**	84484	84484
Clinical Utility (If applicable)	Troponins (I, T, C) are components of cardiac and striated muscle with Troponins I and T being specific cardiomarkers. Troponin T will increase in 3-12 hours as a result of cardiac injury due to ischemia and infarction, and peak in 12-24 hours with a return to normal in 10-15 days. Increases in Tn-T are also observed in chronic renal failure.	Troponin T, High Sensitivity (hs-TnT) - Diagnosis of Acute Myocardial Infarction (MI). Assessment of cardiovascular disease risk.

Test Name	Test Code	Effective Date
Gentamicin Peak, Gentamicin Trough, Gentamicin Random	**0730-2, 1930-7, A616-5**	**Immediately**

Effective immediately, all Gentamicin tests will be retired.

	Previous Test Information
Primary Container	Red
Minimum Volume	1mL
Turn Around Time*	3 days
Transportation Temp	Refrigerate
Stability	7 days
Methodology	Enzyme Immunoassay
Reference Range	1.0-10.0 ug/mL
Collection Instructions	RED: Fill tube, label with patient name__
CPT Code(s)**	**80170x1**
Clinical Utility (If applicable)	Measures therapeutic levels of gentamicin, an aminoglycoside antibiotic

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Test Name	Test Code	Effective Date
Varicella IgG	**0597-5, T008-2**	**Immediately**

This test will be reported as Immune/Non-immune**.**

	Previous Test Information	New Test Information
Primary Container	SST	SST
Minimum Volume	1mL	1mL
Turn Around Time*	1 day	1 day
Transportation Temp	Refrigerate	Refrigerate
Stability	7 days	7 days
Methodology	Chemiluminescence	Chemiluminescence
Reference Range	Immune >164.9 index	Immune
Collection Instructions	SST: Fill tube, invert gently 5 times, label with patient name, let stand for minimum of 30 minutes, maximum of 1 hr, spin for 10-15 minutes	SST: Fill tube, invert gently 5 times, label with patient name, let stand for minimum of 30 minutes, maximum of 1 hr, spin for 10-15 minutes
CPT Code(s)**	**86787x1**	**86787x1**
Clinical Utility (If applicable)	Used to determine immunity	Used to determine immunity

Test Name	Test Code	Effective Date
Varicella IgG	**3117-9**	**Immediately**

This test code will be retired. Please use test code 0597-5 or T008-2.

	Previous Test Information
Primary Container	SST
Minimum Volume	1mL
Turn Around Time*	1 day
Transportation Temp	Refrigerate
Stability	7 days
Methodology	Chemiluminescence
Reference Range	Immune
Collection Instructions	SST: Fill tube, invert gently 5 times, label with patient name, let stand for minimum of 30 minutes, maximum of 1 hr, spin for 10-15 minutes
CPT Code(s)**	**86787x1**
Clinical Utility (If applicable)	Used to determine immunity

Test Name	Test Code	Effective Date
Minimal Residual Disease for CLL/SLL by Flow Cytometry (RETIRED)	**5155-7 (With Interp)** **J496-1 (Tech Only)**	**10/31/2024**

The test codes for CLL/SLL Minimal Residual Disease by Flow Cytometry will be discontinued. The suggested alternative tests, which offer better sensitivity, are:

- TP05-5 OnkoClone CLL MRD by Next-generation Sequencing
  - For follow-up MRD testing in patients with CLL.
- M70-5 IgVH Mutation Analysis by Next-generation Sequencing
  - A prognostic marker for patients with CLL. Hypermutated IgVH is a favorable prognostic indicator in CLL.

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- Used to detect the clone that will be tracked by OnkoClone (TP05-5).

	New Test Information
Primary Container	BLK - Formalin-fixed, Paraffin-embedded Tissue
Turn Around Time*	~7-8 days
Transportation Temp	Room Temperature. Ship block with cold pack during warm weather
Methodology	Genotyping by Next-generation sequencing
Collection Instructions	BLK: This comes in block form from a client with a surgical number imprint
CPT Code(s)**	TP05-5 OnkoClone (81479x1) TM70-5 IgVH Mutation Analysis (81263x1)

Test Name	Test Code	Effective Date
OnkoHRD™	**TQ30-1**	**Immediately**

Please be advised that OnkoHRD™ homologous recombination deficiency (HRD) assessment is now available to all clients nationwide.

OnkoHRD is offered as an add-on test to select OnkoSight Advanced® NGS panels. OnkoHRD can measure genomic scars, which are defined by large-scale genomic instability, such as loss of heterozygosity (LOH), telomeric allelic imbalance (TAI), and large-scale state transitions (LST), in addition to the sequencing of the critical genes involved in the homologous recombination repair (HRR) pathway (e.g., *BRCA1, BRCA2)*.

IMPORTANT: OnkoHRD must be ordered concurrently with OnkoSight Advanced panel (listed below) or within 30 days of the sample receipt date at the laboratory.

- TH53-1: OnkoSight Advanced Gynecological Tumor Panel
- TP57-6: OnkoSight Advanced Breast Cancer Panel
- TK84-0: OnkoSight Advanced Pancreatic and Biliary Tract Tumor Panel
- TH48-2: OnkoSight Advanced Prostate Panel
- TJ16-5: OnkoSight Advanced General Solid Tumor Panel
- TM57-2: OnkoSight Advanced Complete Panel

Requisition forms with OnkoHRD code are now available at our warehouse. To request printed copies, please contact your Account Executive or call the GenPath Customer Service hotline at 800-627-1479.

Healthcare providers should only order panels if each gene or test in the panel is medically necessary.

	New Test Information
Primary Container	BLK - Formalin-fixed, Paraffin-embedded Tissue
Turn Around Time*	~10 days
Transportation Temp	Room Temperature. Ship block with cold pack during warm weather
Methodology	Genotyping by Next-generation sequencing
Collection Instructions	BLK: This comes in block form from a client with a surgical number imprint
CPT Code(s)**	81479x1
Clinical Utility (If applicable)	Clinical indications for Homologous Recombination Deficiency (HRD) testing include patients with ovarian cancer, especially those with high-grade serous ovarian cancer who may benefit from poly (ADP-ribose) polymerase (PARP) inhibitor therapy and breast cancer patients, particularly those with triple-negative breast cancer (TNBC) or HER2-negative breast cancer, as well as pancreatic cancer, advanced prostate, endometrial, and pancreatic neuroendocrine tumors, where it can inform treatment choices. HRD testing may be used to determine eligibility for clinical trials investigating new therapies targeting HRD-related pathways in various cancer types.

Questions? Please contact your Account Executive or Customer Service directly.

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